



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
1098 Gaither Road
Rockville, MD 20850

Ref: FDA Docket No. 2005V-0206
Accession No. 0410970-01

Mr. Carlos A. Guevara
GLOCK, Inc.
P. O. Box 369
Smyrna, Georgia 30081

Dear Mr. Guevara:

In accordance with 21 CFR 1010.4(c)(1), notice is given that the petition from GLOCK, Inc., dated November 30, 2004, for a variance from certain requirements of 21 CFR 1040.10 and 1040.11 is hereby approved. This variance, under the conditions stated below, will allow the introduction into commerce of the Class 3R Tactical Light Module GTL-51 and Tactical Light Module GTL-52 manufactured by GLOCK Gesellschaft m.b.H. in Austria.

A. Variance Number

2005V-0206

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated four (4) years after the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the Glock infrared and visible Class 3R, Tactical Light Module GTL 51 and Tactical Light Module GTL 52.

E. Provisions from Which Variance is Granted

This variance is granted from the following requirements of 21 CFR 1040.10 and 1040.11:

21 CFR 1040.11(b)(3), which restricts the class of alignment laser products such as the Tactical Light Modules GTL 51 and GTL 52 to Class IIIa and specifically limits the levels of invisible infrared wavelengths to Class I.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions under Which Variance is Granted

In lieu of the requirement referred to in Item E above, the following conditions shall apply to the Class 3R, Tactical Light Module GTL 51 and Tactical Light Module GTL 52 visible and infrared laser aiming devices manufactured under this variance.

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1. The products may be classified and labeled as Class 3R laser products in accordance with the IEC 60825-1, Ed. 1.2 (2001) laser standard as permitted under Laser Notice 50 issued July 26, 2001.
2. The infrared laser beams from the models GTL 51 and GTL 52 may also be classified as Class 3R in accordance with the IEC 60825-1, Ed. 1.2 (2001) laser standard.
3. The infrared laser beams from the model GTL 51 and GTL 52 shall not exceed the maximum permissible exposure (MPE) for the unaided eye for an exposure duration of 1 second.
4. Sales to Department of Defense (DOD) agencies of the Glock models GTL 51 and GTL 52 certified under this variance are not permitted in accordance with a request of DOD.
5. The user information to be supplied with each Glock Tactical Light Module shall include:
 - 5.1. Detailed written instructions on the radiation hazards of the tactical light module and on its safe use including warnings against eye exposure for exposure durations in excess of 1 second.
 - 5.2. A statement that sale to agencies of the Department of Defense of products certified under this variance is not permitted by this variance.
 - 5.3. A statement that it is also necessary and intended that the invisible beam emitted by these devices be viewed by the user through night vision equipment.
6. The products incorporate a switch that serves the function of an alternative to the beam attenuator although, in accordance with Laser Notice 50 and IEC 60825-1, Ed. 1.2 (2001) laser standard, a beam attenuator is not required for a Class 3R laser product.
7. The products incorporate a green LED that provides an indication of emission for the invisible infrared laser beam. In accordance with Laser Notice 50 and IEC 60825-1, Ed. 1.2 (2001) laser standard, an emission indicator is not required for a visible Class 3R laser product. The visible beam from these products nevertheless provides indication of emission.

G. Basis for Approval of Variance

The Center for Devices and Radiological Health has determined, in accordance with 21 CFR 1010.4(a), that these infrared aiming laser devices utilize alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard and/or that the specified requirements are not appropriate for laser products for this intended use.

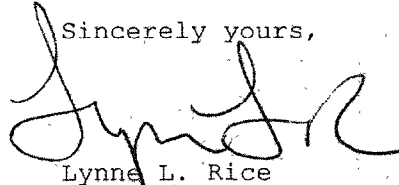
These products satisfy the Class IIIa (and IEC Class 3R) limits for the visible laser beams emitted. The invisible laser beams from the models GTL-51 and GTL-52 exceed the limits of Class I (and IEC Class 1) by less than a factor of 2 and do not exceed the MPE for the unaided eye for an exposure duration of 0.9 seconds.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state, "Conforms to 21 CFR Part 1040 except as authorized by Variance 2005V-0206."

This variance action is available for public disclosure in the Division of Dockets Management, Food and Drug Administration. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,



Lynne L. Rice
Director
Office of Communication, Education,
and Radiation Programs
Center for Devices and
Radiological Health

cc: FDA Division of Dockets Management, Docket No. 2005V-0206